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FORM PTO-1390 (REV 11-2000) DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NO. 700117.401USPC
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see37 CFR 1.5) Unknown 10/009242
INTERNATIONAL APPLICATION NO. PCT/EP00/05273	INTERNATIONAL FILING DATE 07 June 2000 (07.06.00)	PRIORITY DATE CLAIMED 07 June 1999 (07/06.99)

TITLE OF INVENTION
FISTULA BLOCKER

APPLICANT(S) FOR DO/EO/US
BURGARD, Gunther

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☒ is attached hereto
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☒ A English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 – 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4)
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items of information:

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
Unknown 10/009242	**PCT/EP00/05273**	**700117.401USPC**

21. ☒ The following fees are submitted:

Basic National Fee (37 CFR 1.492(a)(1)-(5)):

	CALCULATIONS PTO USE ONLY
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO $1000.00	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO $860.00	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO $710.00	
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)..... $690.00	
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) $100.00	

ENTER APPROPRIATE BASIC FEE AMOUNT =				$860.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				$130.00	
Claims	Number Filed	Number Extra	Rate		
Total Claims	18 - 20 =	0	x $ 18.00	$.00	
Independent Claims	1 - 3 =	0	x $ 80.00	$.00	
Multiple dependent claim(s) (if applicable)			+ $270.00	$270.00	
TOTAL OF ABOVE CALCULATIONS =				$1,260.00	
☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				$.00	
SUBTOTAL =				$.00	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$.00	
TOTAL NATIONAL FEE =				$1,260.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property +				$.00	
TOTAL FEES ENCLOSED =				**$1,260.00**	
				Amount to be refunded:	
				charged	

a. ☒ A check in the amount of $.00 cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. in the amount of $_ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **19-1090**. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

George C. Rondeau, Esq.
Seed Intellectual Property Law Group PLLC
701 5th Avenue, Suite 6300
Seattle, WA 98104-7092
United States of America
(206) 622-4900

George C. Rondeau
SIGNATURE

George C. Rondeau, Jr.
NAME

28,893
REGISTRATION NUMBER

PATENT COOPERATION TREATY

Int'l Application No.	:	PCT/EP00/05273
Int'l Filing Date	:	07 June 2000
U.S. Application No.	:	Not yet known
Inventors	:	BURGARD, Gunther
Title	:	FISTULA BLOCKER
Docket No.	:	700117.401USPC
Date	:	07 December 2001

Box PCT
U.S. Patent and Trademark Office
P.O. Box 2327
Arlington, Virginia 22202-0327

PRELIMINARY AMENDMENT

Sir:

Applicant respectfully requests entry of preliminary amendments in the above-identified United States National Phase patent application. Please amend the claims as follows:

In the Claims:
Please amend Claims 2-18 as follows:

2. Fistula blocker according to claim 1, wherein the closure device (2) has a guide section (6) laid out cranially in the direction of insertion (3).

3. Fistula blocker according to claims 1 and 2, wherein the closure device (2) has a closure section (7) having a bearing surface (4) laid out caudally in the direction of insertion (3).

4. Fistula blocker according to claim 1, wherein the closure device (2) is formed conically.

5. Fistula blocker according to claim 1, wherein the closure device (2) has a concave outer shape.

6. Fistula blocker according to claim 1, wherein the closure device (2) is somewhat shaped like an egg.

7. Fistula blocker according to claim 1, wherein the length of the closure device (2) corresponds in the direction of insertion (3) to about 2 cm, preferably from 0.5 cm to 1 cm.

8. Fistula blocker according to claim 1, wherein the closure device (2) is made of reabsorptive material.

9. Fistula blocker according to claim 1, wherein the closure device (2) is made out of poly-dioxanone, poly-glycolic acid and/or trimethyl-carbonate.

10. Fistula blocker according to claim 1, wherein the closure device (2) is made out of metal, preferably titanium.

11. Fistula blocker according to claim 1, wherein the closure device is hollowed out on the inside.

12. Fistula blocker according to claim 1, wherein the closure device (2) has a semi-permeable surface structure, preferably of membrane.

13. Fistula blocker according to claim 1, wherein the closure device (2) has a spongy structure.

14. Fistula blocker according to claim 1, wherein the closure device (2) is riddled on the inside with channels (12).

15. Fistula blocker according to claim 1, wherein the closure device (2) has several indentations (8) spread out over its surface.

16. Fistula blocker according to claim 1, wherein the fistula blocker (1) is provided with an anchoring device (13) for locking the closure device (2) tight in a fistula passage.

17. Fistula blocker according to claim 16, wherein the anchoring device (13) has several barbed sections (14) blocking its movement contrary to the direction of insertion.

18. Fistula blocker according to claim 17, wherein the barbed sections (14) are restricted in their flexibility, and laid out shored up laterally.

Respectfully submitted,
Seed Intellectual Property Law Group PLLC

George C. Rondeau

George C. Rondeau
Registration No. 28,893

GCR:km
Enclosure: Appendix

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
(206) 622-4900; Fax: (206) 682-6031

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APPENDIX

Claim Amendments

2. Fistula blocker according to claim 1, ~~characterized in that~~ whereinthe closure device (2) has a guide section (6) laid out cranially in the direction of insertion (3).

3. Fistula blocker according to claims 1 and 2, ~~characterized in that~~ wherein the closure device (2) has a closure section (7) having a bearing surface (4) laid out caudally in the direction of insertion (3).

4. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device (2) is formed conically.

5. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device (2) has a concave outer shape.

6. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device (2) is somewhat shaped like an egg.

7. Fistula blocker according ~~to one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the length of the closure device (2) corresponds in the direction of insertion (3) to about 2 cm, preferably from 0.5 cm to 1 cm.

8. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device (2) is made of reabsorptive material.

9. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device (2) is made out of poly-dioxanone, poly-glycolic acid and or tri-methyl-carbonate.

10. Fistula blocker according to ~~one of the claims 1 through 7~~ claim 1, ~~characterized in that~~ wherein the closure device 92) is made out of metal, preferably titanium.

11. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device is hollowed out on the inside.

12. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device (2) has a semi-permeable surface structure, preferably of membrane.

13. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device (2) has a spongy structure.

14. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device (2) is riddled on the inside with channels (12).

15. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the closure device (2) has several indentations (8) spread out over its surface.

16. Fistula blocker according to ~~one of the previous claims~~ claim 1, ~~characterized in that~~ wherein the fistula blocker (1) is provided with an anchoring device (13) for locking the closure device (2) tight in a fistula passage (26).

17. Fistula blocker according to claim 16, ~~characterized in that~~ wherein the anchoring device (13) has several barbed sections (14) blocking its movement contrary to the direction of insertion (3).

18. Fistula blocker according to claim 17, ~~characterized in that~~ wherein the barbed sections (14) are restricted in their flexibility, and laid out shored up laterally.

Fistula blocker

The invention refers to a fistula blocker to clear up a fistula passage, in particular for treatment of anal, bladder, intestinal and urogenital fistulas.

Fistulas are tubular shaped tissue-lined connectors between body cavities or hollow organs amongst themselves or to the surface of the body. They frequently develop as a consequence of infections or accompany abscess formation. For example, anal fistulas arise primarily from an infection of the so-called proctodeal gland. Anal fistulas generally form a connection between the end of the large intestine (rectum) and the outside skin of the buttocks. In doing so, they frequently riddle the sphincter.

In the conventional manner, the majority of anal fistulas are treated with the so-called "lay open" technique. Here the fistula is carefully probed and the tissue lying above it is transected, normally with the sphincter (closing) muscles. Transecting is carried out until the bottom of the separation point is formed by the longitudinally split passage of the fistula. This separation point heals upward from below so that the fistula closes. Due to transecting of the sphincter muscles, however, there is a danger of subsequent incontinence of the patient.

SU 1 718 837 A1 described a method for treating large intestinal fistulas which for example connect the large intestine with the abdominal wall. Here a wire is introduced from the outside up through the inner opening of the fistula. An obturator is guided with the aid of an endoscope through the large intestine to the inner opening. The obturator is attached to the end of the wire and is pulled into the inner opening of the fistula canal so that it closes. Subsequently the wire is removed and the outer opening is closed off with the aid of a separate obturation section. In this way, the fistula path passage is eliminated.

SU 1 204 193 A disclosed an obturator for closing off bronchio-pleural fistulas after pneumectomy treatment. The obturator has a truncated cone shape with an opening at the end of the obverse side. A bulb-headed probe is introduced into the opening on the obverse side with the aid of which the obturator is

introduced into the fistula opening after its surface and the walls of the fistula have been provided with medical glue. With the aid of the glue, the obturator is fastened to the wall of the fistula and the bulb-headed probe is subsequently removed again.

DE 26 37 119 A1 proposes an inflatable balloon as a closure device for closing off blood vessels or fistulas after surgical intervention, it being possible to guide the balloon into the vessel in question, to inflate it and to leave it there. After positioning and inflating the balloon, a hose pipe is separated from the balloon for inflating the latter and pulled out of the body.

The object of the invention is to create a treatment device for clearing up fistulas with which fistulas can be treated as sparingly as possible and where the functions of the adjacent anatomical structures remain as intact as possible.

This object is achieved according to the present invention with a fistula blocker for clearing up a fistula passage with a plug-like closure device which can be at least partially inserted into the fistula passage, and which has a bearing surface which at least to some extent along its circumference can be brought into contact with the wall of a fistula passage perpendicular to the direction of insertion, and in which case the closure device is provided with a flexible application string insertable into the fistula passage, the application string being formed as a drainage pipe.

This fistula blocker makes possible a substantial improvement of operating techniques. After the fistula has been probed, the fistula blocker can be inserted into the opening of the fistula passage and positioned as deeply as required. With the aid of the closure device the fistula passage is closed off as much as possible on one side so that pathogens are blocked off by the closure device on this side. The bearing surface of the closure device is located in inserted condition in contact with the wall of the fistula passage resulting in a certain sealing effect.

The application string can be inserted into the fistula and optionally can pull the closure device with it into the fistula passage. By being designed as a drainage

pipe the application string can at least for a while remain in the fistula. Secretions or pus liquids can be evacuated from the fistula passage via the drainage pipe so that inflammation hotbeds can be removed to the outside. As a drainage pipe, for instance, one can imagine a drainage thread on which germinating secretions can be led outside from the fistula passage by means of its wick-like action.

The fistula blocker according to this invention makes possible an extremely sparing treatment of the fistula, in particular for adjacent tissue. While according to state-of-the-art techniques, adjacent tissue up to the bottom of the fistula passage was severed, with the fistula blocker a sparing treatment technique is possible which is essentially better tolerated by patients and which hardly impacts on the adjacent anatomical structures.

Preferentially, the closure device can have a guide section laid-out cranially in the direction of insertion. The guide section facilitates insertion of the closure device, in which case it aligns the closure device according to the anatomical trajectory of the fistula passage.

Particularly usefully, the closure device can have a closure section having the bearing surface laid-out caudally in the direction of insertion. With the aid of the closure section, the fistula passage can be blocked. The closure section is preferably located with the bearing surface on the walls of the fistula passage.

More appropriately, the closure device can be formed tapering off conically in the cranial direction. The conical shape makes it easier to insert the closure device with the tapering-off guide end. When the closure device is pushed forward, the fistula passage is slightly spread out, thus the fistula passage is folded out and the closure device with the aid of the bearing surface touches fairly tightly to the fistula's wall.

As a variant of the invention, the closure device can be shaped conically. The conical shape entails a continuously expanding outer diameter of the closure device, so that when inserted in the fistula passage up to the required depth it can be pushed into the fistula opening up to the diameter corresponding to that

of the fistula passage.

The closure device may possibly have a concave outer shape. This is particularly good with a concave expanding cross-section shape of the closure device tending towards the caudal direction, and in the range of which the bearing surface should preferably be laid out, so that that surface can be inserted particularly easily into the fistula opening or attaches itself on the outside to the surroundings of the fistula opening until the fistula passage is blocked.

As a variant of the invention, the closure device can be shaped like an egg.

It is feasible to have the closure device shaped rotationally symmetric to its longitudinal axis.

In accordance with a preferred embodiment, the length of the closure device in the direction of insertion can correspond to about 2 cm, preferably 0.5 to 1 cm. With this length, a fistula passage can be effectively blocked. The bearing surface can be shaped sufficiently long in the direction of insertion in order to effectively block the fistula. A closure device of this length can be worn by a patient for a protracted period of time without any problems.

The closure device can preferably be made of reabsorptive material. In this way, the closure device's material can be broken down over a specific period of time. While the closure device at first blocks the fistula, it is slowly converted by the body in the course of time and ultimately, depending on the type of material, even completely dissolved.

Particularly advantageous is making the closure device out of poly-dioxanone, poly-glycolic acid and/or trimethyl carbonate. These materials can be reabsorbed in the long run and can be slowly broken down by the body itself and absorbed.

It is particularly advantageous to make the closure device of metal, preferably titanium.

Particularly advantageous is to have the closure device hollowed out on the inside. In this way, relatively little alien matter is inserted into the fistula passage. If the hollow structure on the inside of the closure device is accessible from outside, then the closure device can be riddled with the body's own tissue, something that promotes granulation with reabsorptive material.

It is proposed that the closure device have a semi-permeable porous surface structure running from cranial to caudal, preferably as membrane. In this way, substances such as pus and liquid can be led off from the fistula passage through the closure device from cranial to caudal while the penetration of impurities from the outside can be prevented.

The closure device can possibly have a spongy structure. This facilitates reabsorption and granulation of the closure device. With a spongy surface structure of the closure device, the body's own substances can easily penetrate the closure device and convert the latter or decompose it over a longer period of time.

As a variant of the invention, the closure device can be permeated with channels on the inside. This facilitates reabsorption of the closure device.

Advantageously, the closure device should have several indentations spread out over its surface. The indentations increase the grip of the closure device so that the latter is more firmly attached to the wall of the fistula passage. The indentations, e.g. in the form of dimples, furthermore promote reabsorption.

In accordance with a special embodiment, the fistula blocker can be provided with an anchoring device which holds the closure device tight in a fistula passage. In this way, the fistula blocker in the body can be securely fastened even if the patient moves.

It is possible to have the anchoring device have one or more barbed sections blocking movement in the direction opposite that of insertion. With the barbed sections, movement opposite the direction of insertion is inhibited so that the

anchoring device cannot inadvertently slip out of the fistula.

In a special way, the barbed sections can be flexible to a limited extent, laid out to the side of the fistula blocker shoring up itself. In this way, the barbed sections themselves protrude and inhibit any independent movement of the fistula blocker contrary to the direction of insertion.

In order to select a fistula blocker based on this invention appropriate to the size and anatomy of the fistula passage to be treated and to achieve tight fit of the fistula blocker, according to this invention separate fistula blocker stencils can be used. Such fistula blocker stencils for insertion in a fistula passage have a plug-like closure device, insertable at least to some extent in the fistula passage which has a bearing surface which can to at least some extent be placed circumferentially perpendicular to the direction of insertion and in contact with the wall of the fistula passage. Such fistula stencils can be made available in different sizes and shapes so that successively several different closure devices can be tried out on the patient and accordingly a fistula blocker of appropriate size and shape can be selected and ultimately deployed.

The fistula blocker stencils may preferably show a closure device having the previously mentioned specific features of the fistula blocker's closure device.

Embodiment examples of the invention are illustrated in the drawing and are explained below:

Fig 1 shows a side view of a fistula blocker according to this invention according to the first embodiment,

Fig 2 shows an enlarged side view of a fistula blocker according to this invention according to a second embodiment,

Fig 3 shows an enlarged side view of a fistula blocker according to this invention according to a third embodiment,

Fig 4 shows a longitudinal section through a human rectum with adjacent

anatomical structures and a fistula blocker according to this invention inserted, and

Fig 5 shows an enlarged presentation of the right part of Figure 4 with a fistula blocker according to this invention inserted.

In Figure 1, a first embodiment of a fistula blocker 1 according to this invention for sanifying a fistula passage is shown. The fistula blocker has a plug-like closure device 2 which can be inserted into a fistula passage in the direction of insertion 3. The closure device 2 has a conical shape with a caudal thick end and a cranial thin end. The caudal end refers in this sense to the end contrary to the direction of insertion 3 while the cranial end is the end of the closure device 2 pointing in the direction of insertion 3.

The closure device 2 has a bearing surface 4 extending perpendicular to the direction of insertion 3 which is given with the conical shape by the surface of the cone's envelope. This surface is at least in places in contact with the wall of a fistula passage. The conical shape is rotationally symmetric to the longitudinal axis 5 of the closure device 2.

The cranial end of the closure device forms a guide section 6 and the caudal end of the closure device 2 forms a closing section 7 containing the bearing surface 4 and, when the fistula blocker 1 is inserted, is in contact with the wall of the fistula passage.

The outside surface of the closure device has several dimple-like indentations 8. The closure device 2 has on the inside an approximately conically shaped hollow space 9 which is closed off at the end by a wall 10.

At its conically pointed cranial end, the closure device 2 is connected to an application string 11 which is flexible and can be inserted into a fistula passage. The application string is formed as a drainage thread so that it can serve to evacuate liquids out of the fistula. The application string can have a length of about 20 cm.

The closure device 2 has on the outside a semi-permeable surface structure porous in the direction from cranial to caudal and impenetrable in the opposite direction. Its surface can have a corresponding membrane or the entire closure device 2 can be formed like a membrane.

In Figure 2, a second invention embodiment of a fistula blocker 1 is shown. Identical reference symbols designate identical elements so that in this regard reference can be made to the details above unless the following description provides an explanation diverging from it.

The closure device of the fistula blocker 1 according to the second embodiment has a closure section 7 with a concave outer shape expanding outward caudally. With the outer bearing surface 4 the fistula blocker 1 can get into contact with the fistula passage. The cranial guide section 6 of the closure device 2 has a shape which is arched somewhat convex forward and inwardly and which leads to the application string 11. In this way, the closure device 2 has somewhat of a bell shape longitudinally.

The closure device 2 is riddled on the inside with channels which via the channel openings 12 border on the outer surface of the closure device 2.

The closure device 2 is provided with an anchoring device 13 which has several barbed sections 14 distributed longitudinally to the girth and length of the closure device 2. The barbed sections 14 branch off laterally shored up from the closure device 2 and are aligned somewhat contrary to the direction of insertion 3. They are flexible to a limited extent.

In Figure 3 a third embodiment of a fistula blocker 1 according to the invention is shown. Identical reference symbols designate identical sections as in the details abive so that in this regard reference can be made to the description above, unless something diverging from that is said below.

The closure device 2 has a somewhat egg-like shape the slimmer end of which is pointed in the direction of insertion 3. The closure device 2 has a spongy hollow structure which is illustrated in cross-section in the left half of the closure

device 2. The spongy structure is shown in the form of several pores 15 which extend up to the outer surface of the closure device 2. The surface of the closure device 2 likewise has a correspondingly spongy structure. Accordingly, the closure device has a porous hollow structure inside.

In the right half, the closure device 2 is shown from the outside where for reasons of visibility the spongy structure has been deleted. On the outer side, the closure device 2 likewise has a corresponding anchoring device 13 with barbed sections 14.

The fistula blockers 1 of the first to third embodiments have a closure device 2 with a length of about 2 cm, preferably 0.5 to 1 cm, measured in the direction of insertion. They may be made out of reabsorptive material like poly-dioxanone, poly-glycolic acid and/or trimethyl-carbonate.

The closure device can likewise be made out of reabsorptive material like metal, preferably titanium.

In Figure 4 a longitudinal section through the rectum of a human being is shown with adjacent anatomical structures. The anal canal 17 connects to the rectum 16 where between the two there extends the linea dentata 18. At the transition from rectum to the anal canal, there is in the wall the proctodeal gland in the vicinity of which fistula passages increasingly form. Furthermore, in accordance with the anatomical peculiarities there is an inner closure muscle 20, an external closing muscle 21 and a musculus levator ani 22 depicted.

In the left half as examples two fistula passages 23 and 24 are shown which in both cases proceed from the area of the proctodeal gland 19 and extend up to the outside skin of one of the buttocks 25. While the fistula passage 23 runs subcutaneously, the fistula passage 24 extends through the inside closure muscle 20.

In the right half a fistula passage 26 is shown which extends through the inner and external closure muscle 20 and 21, in other words in a so-called trans-sphincter trajectory. All fistula passages have an inner opening 27 proceeding

from the rectum 16 and one outer opening 28 located on the outside buttocks 25.

A fistula blocker 1 has been drawn into the fistula passage 26. The closure device 2 sits tightly in the area of the inner opening 27 where its bearing surface 4 is in close contact with the wall of the fistula passage 26.

The application string 11 extends from the guide section 6 of the closure device 2 through the fistula passage 26 up to and through the outside opening 28 and protrudes outward from there.

In Figure 5 an enlarged illustration of the right portion of Figure 4 is shown. Identical reference symbols designate identical sections so that in this regard reference can be made to the details above.

In Figure 5 the caudal end of the closure device 2 extends somewhat into the rectum 16. This end can be severed off after insertion of the closure device 2, e.g. with an appropriate forceps so that the closure device 2 ends flush with the inside wall of the rectum 16. The closure device 2 corresponds to the first embodiment illustrated in Figure 1.

The application string 11 extends over the entire length of the fistula passage up until the outside opening 28 and protrudes out of the latter for about 1-2 cm.

Below, the methods of impacting and functioning of the embodiments of a fistula blocker according to this invention shown in the drawing are explained in greater detail.

A fistula is first of all probed, in other words an appropriate rod-like instrument is pushed into the fistula passage from the outside opening 28 and the fistula's trajectory is investigated. This instrument is pushed forward until it protrudes from the inner opening 27. Subsequently, the application string is pulled through the fistula passage 26 from the inside opening 27 up to the outside opening 28 until the closure device sticks in the inner opening 27 and the guide section 6 opens into the fistula passage. The closure device 2 is pushed as far as

necessary for it to sit tightly in the fistula passage 26. A caudal end protruding into the rectum 16 can optionally be severed off. The application string 11 extends several centimeters outwards from the outer opening 28.

The closure device 2 closes off the inner opening 27 so that no contamination of the fistula passage can occur from inside. The barbed sections 14 arrest the movement of the closure device so that it does not inadvertently slip into the rectum 16.

The closure device 2 forms a thick closure. It can be made of semi-permeable material so that secretion from the fistula passage can penetrate through it as far as into the rectum.

It is also possible to have the closure section 7 applied so as to insulate on the inner wall of the rectum above the inner opening 27, in other words adjoining the fistula passage on the outside.

The application string serves as a drainage pipe. It is designed as a thread along which secretions, e.g. pus, due to the wick action of the thread are led off to the outside through the outer opening 28. In this way, substances forming germs are led off from the fistula passage so that the latter can heal by itself. The application string can be reabsorptive.

Where the closure device 2 is made of reabsorptive material it can be reabsorbed by the body over a protracted period of time, about 6-12 weeks. This is particularly speeded up if it has a porous spongy surface structure so that it can be slowly converted from the inside by the body's own substances.

Where the closure device 2 is not made out of reabsorptive material it can remain in the fistula passage for a protracted period of time.

Depending on the anatomic peculiarities of the fistula passage, the closure device 2 can also be inserted deeper into the fistula passage than is shown in Figure 5.

The size fitting the fistula opening of the closure device 2 can, for instance, be determined by separate test-fit stencils. These test-fit stencils correspond to the shapes of the closure device 2, as described for the three embodiments, in applicable cases without barbed sections 14. Several stencils of differing sizes are available so that the precise fit is determined for each particular fistula and accordingly a fistula blocker 1 can be selected with a closure device 2 of appropriate size.

The fistula blocker constituting the invention makes possible extremely sparing treatment of a fistula where the invasive intervention of traditional treatments is substantially reduced so that tissue are hardly injured and the patient experiences an extremely sparing treatment of the fistula.

CLAIMS

1. Fistula blocker (1) for clearing up a fistula passage (26) with a plug-like closure device (2) which can at least to some extent be inserted into the fistula passage (26) and which has a bearing surface (4) extending at least partially circumferentially and perpendicular to the direction of insertion (3) and which can be brought into contact with the wall of the fistula passage (26), and where the closure device (2) is provided with a flexible application string (11) which can be inserted into the fistula passage (26), the application string being designed as a drainage pipe.

2. Fistula blocker according to Claim 1,
characterized in that
the closure device (2) has a guide section (6) laid out cranially in the direction of insertion (3).

3. Fistula blocker according to Claims 1 and 2,
characterized in that
the closure device (2) has a closure section (7) having a bearing surface (4) laid out caudally in the direction of insertion (3).

4. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device (2) is formed conically.

5. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device (2) has a concave outer shape.

6. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device (2) is somewhat shaped like an egg.

7. Fistula blocker according to one of the previous Claims,
characterized in that
the length of the closure device (2) corresponds in the direction of insertion (3) to about 2 cm, preferably from 0.5 cm to 1 cm.

8. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device (2) is made of reabsorptive material.

9. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device (2) is made out of poly-dioxanone, poly-glycolic acid and/or trimethyl-carbonate.

10. Fistula blocker according to one of the Claims 1 through 7,
characterized in that
the closure device (2) is made out of metal, preferably titanium.

11. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device is hollowed out on the inside.

12. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device (2) has a semi-permeable surface structure, preferably of membrane.

13. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device (2) has a spongy structure.

14. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device (2) is riddled on the inside with channels (12).

15. Fistula blocker according to one of the previous Claims,
characterized in that
the closure device (2) has several indentations (8) spread out over its surface.

16. Fistula blocker according to one of the previous claims,
characterized in that
the fistula blocker (1) is provided with an anchoring device (13) for locking the closure device (2) tight in a fistula passage (26).

17. Fistula blocker according to Claim 16,
characterized in that
the anchoring device (13) has several barbed sections (14) blocking its movement contrary to the direction of insertion (3).

18. Fistula blocker according to Claim 17,
characterized in that
the barbed sections (14) are restricted in their flexibility, and laid out shored up laterally.

ABSTRACT

In order to create a treatment device for clearing up fistulas with which fistulas can be treated as sparingly as possible, and where the functions of the adjacent anatomical structures are to remain as intact as possible, the invention proposes a fistula blocker for clearing up a fistula passage with a plug-like closure device, at least somewhat insertable into a fistula passage, which has a bearing surface which extends at least in part circumferentially perpendicular to the direction of insertion and which can be brought into contact with the wall of a fistula passage, and where the closure device is provided with flexible application string which can be inserted into the fistula passage, the latter being designed as a drainage pipe.

SU 1 204 193 A discloses an obturator for closing off bronchio-pleural fistulas after pneumectomy treatment. The obturator has a truncated cone shape with an opening at the end of the obverse side. A bulb-headed probe is introduced into the opening on the obverse side with the aid of which the obturator is introduced into the fistula opening after its surface and the walls of the fistula have been provided with medical glue. With the aid of the glue, the obturator is fastened to the wall of the fistula and the bulb-headed probe is subsequently removed again.

DE 26 37 119 A1 proposes an inflatable balloon as a closure device for closing off blood vessels or fistulas after surgical intervention, it being possible to guide the balloon into the vessel in question, to inflate it and to leave it there. After positioning and inflating the balloon, a hose pipe is separated from the balloon for inflating the latter and pulled out of the body.

The Publication WO89/11301 describes a somewhat sponge-like closure device for closing off punctures or incisions after vessel operations, particularly in blood vessels. The closure device is inserted into the blood vessel with the aid of a sleeve which for example has already been used for a catheter, and is pulled through the passage from inside. For pulling it in a thread is available which is pulled outwards and fastened and whose material decomposes after a certain period of time in the body.

The object of the invention is to create a treatment device for clearing up fistulas with which fistulas can be treated as sparingly as possible and where the functions of the adjacent anatomical structures remain as intact as possible.

This object is achieved according to the present invention with a fistula blocker for clearing up a fistula passage with a plug-like closure device which can be at least partially inserted into a fistula passage, and which has a bearing surface

which at least to some extent along its circumference can be brought into contact with the wall of the fistula passage perpendicular to the direction of insertion, and in which case the closure device is provided with a flexible application string insertable into the fistula passage, the string being formed as a drainage pipe.

This fistula blocker makes possible a substantial improvement of operating techniques. After the fistula has been probed, the fistula blocker can be inserted into the opening of the fistula passage and positioned as deeply as required. With the aid of the closure device the fistula passage ... on one side

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PTO/SB/01 (10-01) (modified)

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)		
	Attorney Docket No.	700117.401USPC
	First Named Inventor	Gunther Burgard
	COMPLETE IF KNOWN	
	Application Number	10/009,242
	Filing Date	December 07, 2001
☐ Declaration Submitted with Initial Filing ☒ Declaration Submitted after Initial Filing	Group Art Unit	Not yet known
	Examiner's Name	Not yet known

As the below named inventor(s), I/we hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

FISTULA BLOCKER

(Title of Invention)

the specification of which was filed on (MM/DD/YYYY)	June 07, 2000	the specification of which is attached hereto	
as United States Application Number or PCT International Application Number	PCT/EP00/05273	Express Mail No.	
and was amended on (MM/DD/YYYY) *(if applicable)*			

I/we have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

In addition, I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including material information which became available between the filing date of the prior application and the National or PCT International filing date of the continuation-in-part application, if applicable.

I/we hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Claimed	Certified Copy Attached? YES	NO
29909888.5	DE	June 7, 1999	Y		X
PCT/EP00/05273	WO	June 7, 2000	Y		X

Additional foreign application numbers are not listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

I/we hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application No.	Filing Date (MM/DD/YYYY)	Application No.	Filing Date (MM/DD/YY)

Additional provisional application numbers are not listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Direct all communications to Customer Number **00500**

Name	George C. Rondeau	of SEED INTELLECTUAL PROPERTY LAW GROUP PLLC					
Address	701 Fifth Avenue, Suite 6300						
City	Seattle		*State*	WA	*Zip*	98104-7092	
Country	U.S.A.	*Telephone*	(206) 622-4900	*Fax*	(206) 682-6031		

I/we hereby declare that all statements made herein of my/our own knowledge are true and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Sole or First Inventor:	Gunther Burgard						
Given Name (first and middle [if any])				Family Name or Surname			
Gunther				BURGARD			
Inventor's Signature				Date			
Residence: City	Homburg	State		Country	DE	Citizenship	DE
Post Office Address	Fasanenweg 7						
City	Homburg	State	D-66424	Country	DE		

Additional Inventor:							
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Post Office Address							
City		State		Country			

Additional Inventor:							
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Post Office Address							
City		State		Country			

Additional Inventor:							
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature				Date			
Residence: City		State		Country		Citizenship	
Post Office Address							
City		State		Country			

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